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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|------------------------------|------------------------|
| 10/670,911 | 09/24/2003 | Elly Nedivi | 01997/547002 | 6520 |
| 21559 | 7590 | 08/07/2007 | | |
| CLARK & ELBING LLP 101 FEDERAL STREET BOSTON, MA 02110 | | | EXAMINER WEGERT, SANDRA L | |
| | | | ART UNIT 1647 | PAPER NUMBER |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 10/670,911 | Applicant(s) NEDIVI ET AL. | |
| | Examiner Sandra Wegert | Art Unit 1647 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 May 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18, 20-23, 29, 31, 33, 34, 38, 39 and 41-70 is/are pending in the application.
- 4a) Of the above claim(s) 1-14, 21-23, 29, 31, 33, 34, 38, 39 and 41-58 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15-18, 20, 59-70 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Application, Amendments, and/or Claims

The amendment, filed 18 May 2007, has been entered. Claims 15, 16, 18 and 20 have been amended. Claims 19, 24-28, 30, 32, 35-37 and 40 have been canceled. Claims 1-14, 21-23, 29, 31, 33, 34, 38, 39 and 41-58 have been withdrawn by the examiner. Claims 59-70 are new and read on the elected invention.

It should be noted that Claim 17 has an incorrect status identifier. It was labeled as "withdrawn" in the recent amendment, but in fact is an "original" claim and will be examined as such. Claims 15, 16, 17, 18, 20 and 59-70 are under examination.

Withdrawn Objections and/or Rejections

Claim Rejections-35 USC § 112, first paragraph – "Single means" claims.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of Claims 15-18 and 20 under 35 USC § 112, first paragraph for undue breadth is *withdrawn*. The rejection was made in the previous office action (14 November 2006) because the claims had encompassed all polypeptides that had s-CPG15 activity, even those that were not s-CPG15. Applicants amended independent claims to insert a reference to SEQ ID NO: 1 (s-CPG15), and to more explicitly describe specific CPG15 activities (18 May 2007).

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Claim Rejections- Indefiniteness

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of Claims 15-18 and 20 for claiming a composition of matter having "s-CPG activity" and then not specifying such activity, is *withdrawn*. Applicants amended independent claims to make it clear what is meant by the recited biological activity (18 May 2007).

The rejection of Claims 15-18 and 20 for reciting an acronym that was undefined ("s-CPG15") is *withdrawn*. Applicants amended independent claims to make it clear what is meant by s-CPG15 (18 May 2007).

The rejection of Claim 18, because it seemed to encompass contradictory configurations for the CPG15 protein (bound and soluble) is *withdrawn*. Applicants amended the claim to make it clear that the steps of processing CPG are consecutive, not simultaneous (18 May 2007).

Maintained Objections and/or Rejections

Written Description.

Claims 15-18, 20, 59, 60 and 62-70 are also rejected under 35 U.S.C. 112, first paragraph, for containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. The rejection

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was made over claims 15-18 and 20 in the previous office action (14 November 2006) because the claims embraced all peptides "having s-CPG15 biological activity."

Claims 15-18, 20, 59, 60 and 62-70 are directed to a composition of matter comprising a polypeptide that has s-CPG15 activity. Further claim limitations are presented to an amino acid sequence that has at least 85%, 90%, or 95% sequence identity to SEQ ID NO: 1, to compositions in which c-CPG15 is 85%, 90%, or 95% "pure", and s-CPG15 comprising post-translational modifications.

The specification teaches a polypeptide (SEQ ID NO: 1) and describes it as a member of the family of "candidate plasticity [genes]" involved in cell differentiation, growth, and apoptosis, among other functions (see Lee & Nedivi, 2002, J. Neurosci., 22(5): 1807-1815, submitted by Applicants, 23 May 2005). The Specification also describes experiments in which s-CPG15 was used *in vitro* and *in vivo* to inhibit apoptosis in developing or stressed neurons. However, the specification does not teach functional or structural characteristics of all peptides that have at least 85%, 90%, or 95% sequence identity to SEQ ID NO: 1, or compositions in which c-CPG15 is 85%, 90%, or 95% "pure." The description of one polypeptide (SEQ ID NO: 1) that does have s-CPG15 activity is not adequate written description of an entire genus of functionally equivalent polypeptides and compositions.

Applicants do not discuss the Written Description rejection presented in the Office Action of 14 November 2006, but instead discuss the breadth rejection, which is withdrawn (see above). However, as stated in the previous Office Action, applicants must be in possession of whatever invention is claimed (*Vas-Cath Inc. v. Mahurkar*, 19USPQ2d 1111). The specification does not "clearly allow persons of ordinary skill in

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the art to recognize that [he or she] invented what is claimed” (See *Vas-Cath* at page 1116).

To provide evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claim is a partial structure in the form of a recitation of percent identity or purity of the composition. There is not even identification of any particular portion of the structure that must be conserved. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

With the exception of SEQ ID NO: 1, the skilled artisan cannot envision the detailed chemical structure of the encompassed polypeptides and compositions that have s-CPG15 activity, and therefore, would not know how to make or use them. Conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of making or use. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of use. The polypeptide *itself* is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

Therefore, only the purified polypeptide of SEQ ID NO: 1, but not the full breadth of the claims, meets the written description provision of 35 U.S.C. §112, first paragraph.

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In addition, Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Claim Rejections-Prior Art

The following are quotations of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of Claims 15-18 and 20 under 35 U.S.C. 102(b) for being unpatentable over Zhou, et al, (5 April 2000, Accession No. AAF62371) is *maintained*. This rejection also applies to new claims 59-70. Zhou, et al disclose a polypeptide that, within residues 28-114, bears 100% homology to SEQ ID NO: 1 of the instant Application (see alignment of record, 14 November 2006). The protein of the instant application is 87 amino acids in length. The polypeptide disclosed in Zhou, et al, comprises the entire sequence of SEQ ID NO: 1 plus additional residues at either end. This reference thus anticipates Claims 15-18, 20 and 59-70 in their entirety, since the independent claim recites "comprising" SEQ ID NO: 1. Applicants argue that SEQ ID NO: 1 is the soluble form of CPG15 (18 May 2007, p. 8). However, the claims embrace the full-length molecule because they recite "polypeptides *comprising* [] SEQ ID NO: 1".

Claims 15-18, 20 and 59-70 are rejected under 35 U.S.C. 102(b) for being unpatentable over Naeve, et al (1997, Proc. Natl. Acad. Sci., 94: 2648-2653). Naeve, et

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al disclose a polypeptide that bears 100% homology to SEQ ID NO: 1 of the instant Application at residues 28-114. In the publication, they refer to the polypeptide as "neuritin" and Accession No. U88950, but it appears to be non-soluble CPG. The authors measured neuronal arborization caused by neuritin in hippocampal neurons, among other developmental experiments. Applicants argue that SEQ ID NO: 1 is the soluble form of CPG15 (18 May 2007, p. 8). However, the Naeve, et al publication discusses removal of the neuritin/CPG GPI "anchor" sequence, as recited in claim 16 (p. 2649, paragraph 5), and maintains that soluble CPG15 is as effective as membrane-bound CPG15 in causing neuronal differentiation (p. 2653, 1st paragraph). The reference anticipates 15-18, 20 and 59-70 in their entirety, since claim 15 recites "comprising" SEQ ID NO: 1, and all claims embrace full-length CPG/neuritin. In addition, the reference anticipates the claim that explicitly recites CPG15 with the GPI anchor truncated (Claim 16).

Claims 15-18, 20 and 59-70 are also rejected under 35 U.S.C. 102(b) as being unpatentable over Nedivi, et al (1998, Science 281: 1863-1866). Nedivi, et al, disclose a polypeptide that bears 100% homology to SEQ ID NO: 1 of the instant Application at residues 28-114. In other words, SEQ ID NO: 1 corresponds to the disclosed Nedivi, et al peptide at residues 28-114. In the publication, the authors refer to the polypeptide as "CPG15." The authors measured dendritic elaborization caused by CPG15 in the developing *Xenopus* tectum, and discovered that CPG15 is also involved in cell-to-cell communication of developing neurons. The publication discussed removal of the GPI-linkage sequence, as recited in claim 16, but stated that the soluble form is not as effective as the membrane-bound form in causing dendritic arborization (p. 1865, 1st paragraph). The Nedivi reference still anticipates Claims 15-18, 20 and 59-70 in their

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entirety, since claim 15 recites a composition "comprising" SEQ ID NO: 1. In addition, the reference anticipates the claim that explicitly recites truncated CPG15 (Claim 16).

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Wegert whose telephone number is (571) 272-0895. The examiner can normally be reached Monday - Friday from 9:00 AM to 5:00 PM

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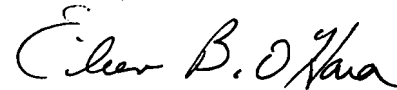
(Eastern Time). If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Nickol, can be reached at (571) 272-0835.

The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (in USA or CANADA) or 571-272-1000.

SLW

31 July 2007



EILEEN B. O'HARA
PRIMARY EXAMINER